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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 109305	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/000960	International Filing Date (day/month/year) 30 July 2003	Priority Date (day/month/year) 30 July 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A01K 11/00; G01N 1/08		
Applicant AG-ID PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 19 February 2004	Date of completion of the report 16 November 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer A. SEN Telephone No. (02) 6283 2158

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Preliminary Examination Authority has found that there are different inventions as follows:

1. Claims 1-17 are directed to a sampling device characterised by a male portion, female portion and a sample removal means being provided with an amount of sample preservative or preservative that is available to the sample within a sample receiving space. It is considered that the underlined feature comprises a first "special technical feature".
2. Claims 18-20 are directed to a sampling device characterised by a male portion comprising a base and an upstanding member and a female portion comprising a first female base portion and a cap including a resilient ring retained therebetween to prevent and/or detect tampering. It is considered that the underlined feature comprises a second "special technical feature".

These groups are not so linked as to form a single general inventive concept, that is, they do not have any common inventive features, which define a contribution over the prior art. The common concept linking together these groups of claims is providing a sampling and tagging system simultaneously. However this concept is not novel in the light of any of the citations listed in the International Search Report, especially WO 02/39810, DE 20101015 U1, DE 20022647 U1 and EP 1060662. Therefore these claims lack unity a posteriori.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-22	YES
	Claims	NO
Inventive step (IS)	Claims 1-22	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-22	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

All the documents cited in the ISR were category A only.

Claims 1-22 meet the criteria set forth in PCT Article 33(2)-(4) for novelty, inventive step and industrial applicability. The prior art published before the priority date does not disclose, teach or suggest, singly or in combination, either of the following inventions:

(a) a sampling device comprising a male portion, female portion and a sample removal means being provided with an amount of sample preservative or preservative that is available to the sample within a sample receiving space

(b) a sampling device comprising a male portion comprising a base and an upstanding member and a female portion comprising a first female base portion and a cap including a resilient ring retained therebetween to prevent and/or detect tampering

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 1 lacks clarity in that there is no prior reference to 'the aperture'. I have a similar objection to Claims 12 and 14. Please also note that Claim 12 defines the aperture as 'provided in the base member of the first female base portion', while Claim 14 defines the aperture as 'provided in the first female base portion'. Both apertures appear to be the same but have been defined differently.

2. Claim 18 lacks clarity in that it is named as a 'sampling' device and yet there is no feature defined that allows or enables any sort of sampling to take place. The features defined are, overall, that of an ear cutter.

Claim 19 lacks clarity for a similar reason. The last bit of definition 'sampling components' does not make it clear to the reader as to how these 'sampling components' fit in with the other features and is left somehow as an 'add-on' that does not cohere with the rest of the claim. Furthermore, the words 'the use' (of these components) seems to indicate that it is a method claim and yet the claim at its beginning appears to be a claim to the device per se.

3. Claims 1-22 do not define the invention described because they omit the following feature which, from reading the specification as a whole, appears to be essential to the invention:

(a) the action of bringing the male and female portions together obtains a biological sample from an animal and tags the animal simultaneously

It is abundantly clear from your description (eg page 2, lines 17-20; each and every preferred embodiment) that it is your intention to carry out a 'simultaneous' procedure so that samples from different animals do not get mixed up.

There is absolutely nothing defined in Claim 1, say, to indicate this. There is nothing to indicate that the *device stays on the animal even after the sample container is removed (ie the animal is tagged)*. Without this, the claim omits the very crux of your invention. Hence this feature must be defined.

4. In addition to the above Item 3, Claims 18 and 19 do not define the invention described because they also omit the following features which, from reading the specification as a whole, appear to be essential to the invention:

(a) the features as in Claim 20

As Claims 18 and 19 stand, there is no sample container defined, there is no sample removal means defined. How then can these claims define the invention you have described? It is absolutely clear from your description that your invention must have at least these two components and these components must in turn interact as defined in Claim 20. The claims must therefore define these features. This objection is probably associated with the clarity objections in Item 2 above.